

SJ-EXHIBIT 17

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION : :
9 : :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 : :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 VOLUME I

16 - - -

17 April 17, 2019

18 - - -

19 Videotaped deposition of
20 THOMAS PREVOZNIK, taken pursuant to
21 notice, was held at the law offices of
22 Williams & Connolly, 725 12th Street,
23 Washington, D.C., beginning at 9:11 a.m.,
24 on the above date, before Michelle L.
25 Gray, a Registered Professional Reporter,
26 Certified Shorthand Reporter, Certified
27 Realtime Reporter, and Notary Public.

28 - - -

29 GOLKOW LITIGATION SERVICES
30 877.370.3377 ph | 917.591.5672 fax
31 deps@golkow.com

1 system in use by wholesale drug
2 distributors for controlled substances,
3 do you see that reference that you just
4 read?

5 A. Yes.

6 Q. Is it fair to say then,
7 there was in fact at this point in time,
8 in 1998, a DEA-approved suspicious order
9 monitoring system for controlled
10 substances?

11 A. I would say no, because
12 there was never a -- DEA never had an
13 approved system. The system that the
14 statute requires and the regulations
15 require is the registrant is to design
16 and operate that system.

17 They come to us and they
18 say, here's our system, and we may have
19 discussions with them about it. So you
20 can have a great system in paper, but
21 when you implement it, are you actually
22 implementing what you say.

23 So that's part of our job,
24 when we go out there for schedule

1 investigation, is to look at that program
2 and are they doing what they're saying,
3 is it actually detecting suspicious
4 orders.

5 Q. So, Mr. Prevoznik, try to
6 listen to my question and answer it. I
7 realize that you would like to speechify
8 a little bit and get out your talking
9 points, but please restrain --

10 MR. FINKELSTEIN: Try not to
11 argue with the witness.

12 BY MS. MAINIGI:

13 Q. -- from doing that.

14 MR. FINKELSTEIN: You can
15 ask your questions. And you're
16 not here to abuse him.

17 BY MS. MAINIGI:

18 Q. So, Mr. Prevoznik, let's
19 back up. The DEA helped to write this
20 report, right?

21 A. Correct.

22 Q. And someone from the office
23 of diversion control at the DEA was in
24 fact the chair of the group that wrote

1 Q. And did you read far enough
2 in the report to see that there was, in
3 fact, an algorithm that was contained as
4 an exhibit to the report?

5 A. Do you have a page number?

6 Q. Sure: Bates Number 2247.

7 Did you review this page
8 previously?

9 A. Yes.

10 Q. Okay. And -- and this page
11 essentially contains a calculation or
12 algorithm for both List I chemicals and
13 Schedule II controlled substances,
14 correct?

15 A. Correct.

16 Q. Now, DEA did not require
17 distributors to use a particular
18 algorithm or metric to identify excessive
19 purchases of controlled substances,
20 correct?

21 A. Could you please repeat
22 that?

23 Q. DEA did not require that a
24 distributor use a particular calculation

1 or algorithm to identify excessive
2 purchases of controlled substances,
3 correct?

4 A. Correct.

5 Q. But, the DEA was aware that
6 certain registrants were using a
7 calculation or metric or algorithm to
8 identify an excessive purchase, correct?

9 MR. FINKELSTEIN: Objection.
10 Vague as to time.

11 THE WITNESS: I -- I just
12 want to make sure I'm clear on
13 this. We're talking about
14 excessive purchases or are we
15 talking about suspicious orders?

16 BY MS. MAINIGI:

17 Q. Well, right now I'm talking
18 about excessive purchase reports in this
19 time period.

20 Was the DEA aware that in
21 approximately the 1998 time period, that
22 distributors were using a particular
23 algorithm or calculation to identify
24 excessive purchases of controlled

1 We -- we established before
2 that the DEA today does not review
3 reporting systems, right?

4 MR. FINKELSTEIN: Objection.
5 Mischaracterizes the witness's
6 testimony.

7 THE WITNESS: I mean, we --
8 we reviewed McKesson's, the new
9 one.

10 BY MS. MAINIGI:

11 Q. And you left it --

12 A. -- we reviewed it, we -- we
13 did not -- we --

14 MR. FINKELSTEIN: Let the
15 witness answer the question.

16 THE WITNESS: I don't know
17 what you mean by the term
18 "blessing it."

19 BY MS. MAINIGI:

20 Q. Okay.

21 A. Because as I had said
22 previously, that you -- you can write the
23 best system in the world, but if you
24 don't implement it and you don't stick to

1 it, it doesn't mean anything.

2 So that's part of our
3 review, when we go out and do schedule
4 investigations, is to review, are they
5 factually, in fact -- did -- is -- are
6 they operating a system that can detect a
7 suspicious order.

8 BY MS. MAINIGI:

9 Q. And that's something that
10 the DEA reviews periodically as part of
11 its auditing process, correct?

12 A. Correct.

13 Q. So as part of the audit
14 process, operating systems that are
15 designed to review suspicious orders are
16 reviewed by the DEA?

17 A. Well, it's not just the
18 schedule. I mean it could be a
19 pre-registration, somebody is coming on
20 and they have -- we have to go through
21 the whole public interest of, you know,
22 what do you have in place to operate and
23 detect a system. So it's not just a
24 schedule investigation. There are

1 schedule investigations that we follow
2 up, and we do that as well. So it comes
3 in -- it comes in various times that
4 we're going to review somebody's
5 operating system, whether we're on
6 schedule investigation, or whether we're
7 doing an investigation on a pharmacy or
8 something like that, where we're going to
9 look at how many SORs were submitted or
10 not submitted, or we're going to look at
11 the ARCOS data, how much did they buy.

12 We're going to look at
13 various things to make the determination
14 on what is going on.

15 Q. And if either in the
16 pre-registration process or in the audit
17 process the DEA determines that a
18 registrant's system is not adequately
19 detecting suspicious orders, is that
20 something that is conveyed to the
21 registrant?

22 A. Yeah, we -- we would tell
23 them, you need to add something.

24 Q. It's clear in the Rannazzisi

1 be a phone call? What forms do you
2 recall?

3 MR. FINKELSTEIN: Objection.
4 Vague as to time.

5 THE WITNESS: I don't -- I
6 don't remember off the top of my
7 head what it looked like. It was
8 usually -- back then it was paper.

9 BY MS. MAINIGI:

10 Q. Is it fair to say that from
11 time to time you might get a report of a
12 suspicious order via a telephone call
13 from a distributor?

14 MR. FINKELSTEIN: Objection.
15 Vague as to time.

16 THE WITNESS: I'm not aware.
17 BY MS. MAINIGI:

18 Q. When you say --

19 A. It could be chemical, we
20 might have somebody call.

21 Q. But you don't think a
22 suspicious order for a controlled would
23 come in via a telephone call?

24 MR. FINKELSTEIN: Objection.

1 distributor initiative meetings through
2 today, right?

3 A. I don't know if we have any
4 today. But we've done some recently,
5 yes.

6 Q. Okay. The more recent ones,
7 where is the focus and where is the
8 trends?

9 A. Well, I think what we've
10 been showing, and as it's been reported,
11 we're seeing a decline in the number of
12 opioid prescriptions. We've seen
13 increase in amphetamines and
14 methylphenidate. We're seeing -- the one
15 opioid we still see an increase in is
16 Suboxone, buprenorphine, for drug
17 treatment. We're seeing a little bit of
18 shift of the drugs.

19 Q. So the trends and the
20 problem areas are unfortunately always
21 changing and shifting. Is that fair?

22 A. Well, there tends to be a
23 shift, yeah.

24 Q. And the DEA does its best to

1 try to identify the changes and the
2 shifts in the trends, correct?

3 A. Well, I mean, the data --
4 the data shows that, so it's not DEA
5 doing it. You know, there's been a lot
6 of hard work by a lot -- a lot of
7 different people, including the industry.
8 So...

9 Q. The data from the industry
10 helps everyone identify the shifts in the
11 trends, correct?

12 A. Yeah.

13 Q. Including the DEA?

14 A. Yeah. Yes.

15 Q. And because of the shifts in
16 the trends and the fact that there is a
17 constant change, is that one of the
18 reasons why the DEA takes the position
19 that registrants must design their own
20 system for suspicious order monitoring
21 and reporting?

22 MR. FINKELSTEIN: Objection.

23 Vague.

24 THE WITNESS: I don't think

1 the characterization.

2 THE WITNESS: Nationwide,
3 correct.

4 BY MS. MAINIGI:

5 Q. Instead, one-off guidance
6 was perhaps provided in the context of
7 individual distributor meetings, correct?

8 A. Yes. Along with the MOAs
9 and the settlements that were done.

10 Q. And is there documentation
11 of what was said at the individual
12 distributor meetings?

13 A. It would be the PowerPoints
14 and the report -- after report.

15 Q. And this is an internal DEA
16 report?

17 A. Yes.

18 Q. And have you reviewed those
19 internal DEA reports for the purpose of
20 preparing for your testimony today?

21 A. Some of them.

22 Q. Now, does the DEA agree that
23 there's more than one way to design and
24 operate a system that can identify and

1 report suspicious orders?

2 A. Yes.

3 Q. And there's no single
4 feature that makes a suspicious order
5 monitoring system compliant, correct?

6 A. Correct.

7 Q. And the DEA leaves it up to
8 the registrant to design a system that
9 works with its own business model and
10 customer base, correct?

11 A. Correct.

12 Q. Does it matter to the DEA
13 whether a registrant reviews orders
14 manually or uses an automated system?

15 A. No, it doesn't matter.

16 Q. Other than requiring that
17 the report, suspicious order report
18 clearly indicate that the order is
19 suspicious, does DEA require suspicious
20 order reports to follow a particular
21 format?

22 A. That's correct.

23 Q. Let me ask the question
24 again. The DEA does not require

1 that this is outside the scope.

2 I'll let the witness answer for
3 now if you have understanding.

4 THE WITNESS: Yes.

5 BY MR. STEPHENS:

6 Q. Is it also true under -- you
7 testified earlier today about the C.F.R.
8 regulations, correct?

9 A. Correct.

10 Q. And under Title 21 -- or I'm
11 sorry, under 21 C.F.R. 1301.71(b), it's
12 true that the regulation regarding
13 suspicious order monitoring does not
14 require strict compliance, it requires
15 substantial compliance?

16 MR. FINKELSTEIN: Did you
17 mean 74?

18 MR. STEPHENS: It might be
19 74.

20 MR. FARRELL: 1301.74(b)?

21 MR. STEPHENS: Yes. No,
22 actually -- here. Let me just
23 mark it.

24 (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-13.)

3 BY MR. STEPHENS:

4 Q. I'll show the witness what's
5 been marked as Exhibit 13.

6 A. So, (b)?

7 Q. (B), right.

8 A. Okay.

9 Q. So (b) states substantial
10 compliance with the standards set forth,
11 right?

12 A. Yes.

13 Q. Okay. And that could be
14 deemed sufficient, correct?

15 A. Yes. That's what it says.

16 Q. It does not say strict
17 compliance, correct?

18 A. Correct.

19 Q. Like manufacturers and
20 distributors, DEA also considers doctors
21 who prescribe opioids to their patients
22 to be registrants?

23 A. Correct.

24 Q. Okay. The prescribing

1 MR. FINKELSTEIN: Scope.

2 THE WITNESS: Can you please
3 repeat it.

4 BY MR. STEPHENS:

5 Q. Sure. As to prescription
6 opioids, DEA believes that the
7 overwhelming majority of prescribing in
8 America is conducted responsibly?

9 A. Yes, correct.

10 Q. And DEA has stated that
11 99.5 percent of prescribers do not
12 overprescribe opioids?

13 MR. FINKELSTEIN: Scope.

14 You can answer if you know.

15 THE WITNESS: I don't know
16 that we said 99.5 percent. I've
17 heard the figure 1 to 2 percent.

18 BY MR. STEPHENS:

19 Q. Okay. Well, let me show you
20 the transcript.

21 MR. FARRELL: Can you
22 reference the transcript, please.

23 MR. STEPHENS: Yes, sir.

24 (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-14.)

3 BY MR. STEPHENS:

4 Q. The transcript is dated
5 April 29, 2014. It's a subcommittee
6 hearing on oversight investigations by
7 the Committee of Energy and Commerce.

8 MR. FINKELSTEIN: We're at
9 6:00. I'll let you ask this
10 question and then we're going to
11 break for the day.

12 BY MR. STEPHENS:

13 Q. I'd ask you to turn to Page
14 76.

15 A. Page 76.

16 Q. Page 76, Mr. Prevoznik. And
17 we're looking at, like, the
18 second-to-last paragraph where
19 Mr. Rannazzisi is talking.

20 Do you see that?

21 A. Mm-hmm.

22 Q. And there's a question from
23 a Mr. Burgess ahead of that, correct?

24 Do you see that?

1 A. Yes.

2 Q. Okay. And Mr. Burgess says
3 something to the effect that
4 Mr. Rannazzisi seems to imply that we are
5 overprescribing. Mr. Rannazzisi then
6 responds and says, "I think that if you
7 are talking about 99.5 percent of the
8 prescribers, no, they are not
9 overprescribing. But our focus is in
10 rogue pain clinics and rogue doctors who
11 are overprescribing."

12 Did I read that accurately?

13 A. Yes.

14 Q. Okay. So my question for
15 you, the initial question was, DEA has
16 publicly stated that 99.5 percent of the
17 prescribers are not overprescribing,
18 correct?

19 A. Correct.

20 MR. STEPHENS: All right.
21 That's all I have for the day.

22 MR. FINKELSTEIN: We're
23 going to excuse the witness so we
24 can argue about what's going to

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4 - - -
5

6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :
13

14 - HIGHLY CONFIDENTIAL -

15 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

16 VOLUME II
17 - - -
18

19 April 18, 2019
20 - - -
21

22 Continued videotaped
23 deposition of THOMAS PREVOZNIK, taken
24 pursuant to notice, was held at the law
 offices of Williams & Connolly, 725 12th
 Street, Washington, D.C., beginning at
 8:16 a.m., on the above date, before
 Michelle L. Gray, a Registered
 Professional Reporter, Certified
 Shorthand Reporter, Certified Realtime
 Reporter, and Notary Public.

25 - - -
26 GOLKOW LITIGATION SERVICES

27 877.370.3377 ph | 917.591.5672 fax
28 deps@golkow.com
29

1 A. Acting administrator.

2 Q. Acting administrator.

3 A. Right.

4 Q. It's the number one position
5 at DEA?

6 A. Correct.

7 Q. Okay. So here Mr. Patterson
8 was asked a question, and in part of his
9 response he says, "But I go back to the
10 fact that I look at the vast majority of
11 doctors, 99.99 percent are all trying to
12 do right by their patients."

13 Do you see that?

14 A. Correct.

15 Q. Did I read that accurately?

16 A. Yes.

17 Q. Okay. DEA agrees, as of
18 2018, that 99.9 percent of doctors are
19 all trying to do right by their patients,
20 right?

21 MR. FINKELSTEIN: Scope.

22 THE WITNESS: I don't -- I
23 mean, he's stated that, but I
24 don't think it's a static number.

1 So I mean, I think -- it will
2 fluctuate depending on what a
3 prescriber eventually does.

4 BY MR. STEPHENS:

5 Q. Okay. As of --

6 A. As of that date, that's what
7 was said, yes.

8 Q. Okay. He was the number one
9 person at DEA when he made that
10 statement, right?

11 A. Right.

12 MR. FINKELSTEIN: Asked and
13 answered.

14 MR. FARRELL: Excuse me.
15 Could you please repeat the
16 exhibit number?

17 MR. STEPHENS: Sure. That's
18 number 15, Paul.

19 MR. FINKELSTEIN: And wait
20 for my objections.

21 BY MR. STEPHENS:

22 Q. Mr. Prevoznik, if
23 99.99 percent of prescribers acted
24 appropriately, the diversion problems DEA

1 speculating on that, but, yes.

2 BY MR. STEPHENS:

3 Q. Okay. I'd like to continue
4 by asking you some additional questions
5 about interpretation enforcement of
6 Title 21 U.S.C. 23, the regulations and
7 how those relate to the design of a
8 reasonable SOMs system. Okay?

9 A. Yes.

10 Q. Okay. So yesterday you --
11 you testified about different
12 distributors having different business
13 models, right?

14 A. Correct.

15 MR. FINKELSTEIN: Objection.

16 Scope. Characterization.

17 BY MR. STEPHENS:

18 Q. Is it fair to say that a
19 SOMs systems is not a one-size-all
20 proposition, one-size-fits-all
21 proposition?

22 A. Correct.

23 Q. And DEA understands that not
24 all registrants distribute opioids to the

1 same customers, right?

2 A. Correct.

3 Q. DEA understands that
4 registrants have different business
5 models?

6 A. Correct.

7 Q. And DEA expects that each
8 registrant will review its own business
9 model and design a SOM system that fits
10 its specific method of distribution?

11 MR. FINKELSTEIN: Objection.
12 Vague.

13 THE WITNESS: That's correct
14 as -- as per the regulations.

15 BY MR. STEPHENS:

16 Q. Okay. Some registrants
17 distribute to hospitals?

18 A. Correct.

19 Q. Some don't?

20 A. Correct.

21 Q. Some registrants distribute
22 to hospice centers?

23 A. Correct.

24 Q. Some don't?

1 right?

2 MR. FINKELSTEIN: Wait.

3 Scope, calls for speculation.

4 THE WITNESS: Not to my
5 knowledge.

6 BY MR. STEPHENS:

7 Q. Okay. CVS, Walgreens, Rite
8 Aid, HBC Giant Eagle, they never had a
9 ratio of controlled to noncontrolled
10 substances that was 95 percent controlled
11 to 5 percent non-controlled, right?

12 MR. FINKELSTEIN: Scope.
13 Calls for speculation.

14 THE WITNESS: Not to my
15 knowledge.

16 MR. FINKELSTEIN:
17 Mr. Videographer, what's our
18 on-the-record time?

19 THE VIDEOGRAPHER:
20 42 minutes.

21 MR. FINKELSTEIN: We're past
22 seven hours. So everybody knows.

23 BY MR. STEPHENS:

24 Q. DEA has acknowledged and has

1 acknowledged in presentations that it
2 gave that no chain pharmacies were rogue
3 pharmacies, right?

4 A. Correct.

5 MR. FINKELSTEIN: Hang on
6 one second. I am just reading the
7 question.

8 Okay.

9 BY MR. STEPHENS:

10 Q. Your answer was "correct,"
11 right?

12 A. Yes.

13 Q. Walmart, CVS, Rite Aid,
14 Walgreens, HBC Giant Eagle are all chain
15 pharmacies, true?

16 A. True.

17 Q. DEA is generally aware that
18 Walmart only distributes controlled
19 substances to its own Walmart store
20 pharmacies, right?

21 MR. FINKELSTEIN: Objection.

22 Scope. Calls for speculation.

23 THE WITNESS: Well, that
24 just changed. But prior to the

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 _____) Case No.
8) 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 FRIDAY, MAY 17, 2019

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of Thomas
18 Prevoznik, Volume III, held at the offices of
19 WILLIAMS & CONNOLLY LLP, 725 Twelfth Street,
20 NW, Washington, DC, commencing at 8:10 a.m.,
21 on the above date, before Carrie A. Campbell,
22 Registered Diplomate Reporter and Certified
23 Realtime Reporter.

24 - - -

25 GOLKOW LITIGATION SERVICES
26 877.370.3377 ph | 917.591.5672 fax
27 deps@golkow.com

1 to Walmart stores.

2 QUESTIONS BY MS. FUMERTON:

3 Q. And your other commentary after
4 you said "yes" was simply pure speculation on
5 your part, correct?

6 A. Correct.

7 Q. Walmart was not a wholesale
8 distributor of controlled substances,
9 correct?

10 MR. FINKELSTEIN: Scope.

11 THE WITNESS: What do you mean
12 by that?

13 QUESTIONS BY MS. FUMERTON:

14 Q. Well, various terms have been
15 used by plaintiffs when asking questions, and
16 what I'm distinguishing between are
17 distributors who distribute the wholesale to
18 many different pharmacies, independent and
19 the like, and a distributor like Walmart that
20 only self-distributes controlled substances.

21 Do you understand that
22 distinction?

23 A. Yes, correct.

24 Q. Okay. So under that
25 distinction, Walmart is not a wholesale

1 distributor of controlled substances,
2 correct?

3 MR. FINKELSTEIN: Scope.

4 THE WITNESS: Correct.

5 QUESTIONS BY MS. FUMERTON:

6 Q. And that's true for Rite Aid as
7 well, correct?

8 MR. FINKELSTEIN: Scope.

9 THE WITNESS: Yes.

10 QUESTIONS BY MS. FUMERTON:

11 Q. And Walgreens, CVS and HBC
12 Giant Eagle, correct?

13 MR. FINKELSTEIN: Scope.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. FUMERTON:

16 Q. And would you agree that
17 nonmembers -- well, let me strike that.

18 You would agree that there may
19 be reasons why nonmembers of HDMA do not need
20 to follow HDMA guidelines, correct?

21 MR. FINKELSTEIN: Scope.

22 Vague.

23 THE WITNESS: I don't even know
24 that the HDMA members have to follow
25 the guidelines either. I mean, the